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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,073	12/20/2001	William C. Dengler	2824/1	9825

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EXAMINER	
BLECK, CAROLYN M	

ART UNIT	PAPER NUMBER
3626	

DATE MAILED: 09/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/027,073	DENGLER, WILLIAM C.
	Examiner	Art Unit
	Carolyn M Bleck	3626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 May 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-26 and 29-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-26 and 29-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Notice to Applicant

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 18 May 2004 has been entered.

2. This communication is in response to the RCE filed 18 May 2004. Claims 14-26 and 29-32 are pending. Claims 14 and 29 have been amended.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 14-26 and 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans (5,924,074) in view of Detjen et al. (5,970,466), Joao (6,283,761), and Coli et al. (6,018,713).

(A) As per claims 14-15, 21-23, and 26, Evans discloses an electronic medical records system for storage and retrieval of electronic medical records in a computer environment, such as a local or wider area network including portable computers (Abstract; col. 1 lines 5-10) comprising:

(a) a medical records system (Abstract) including:

(i) a patient data repository in communication with a point of care system to store and organize the patient data for access by the point of care system, wherein the patient data repository comprises a server computer having access to patient data stored in a relational database that accepts SQL data queries, wherein the point of care system captures patient data at a point of care by health care providers such as physicians or nurse practitioners from patients and communicates the patient data to the patient data repository (Fig. 1, 24, col. 2 lines 44-64, col. 12 line 55 to col. 14 line 25, and col. 16 lines 1-53);

(ii) an input device such as keyboard, a mouse, or an electronic pen, for permitting a health care provider to enter, access, process, analyze, and annotate data from patient records in real-time at the point of care (col. 5 lines 1-28 and col. 7 lines 5-40);

(iii) desktop computers, laptop computers, or wireless pen computers communicating through the world wide web portion of the Internet, WAN, or LAN (reads on "global communications network") with the patient data repository or database on the server for providing instant access to a patient's electronic medical record by authorized healthcare providers from any geographical location in order to analyze patient

information to identify medication interactions and allergies and to enter patient diagnoses, procedure codes, and the administration of treatments (col. 5 lines 29-55, col. 11 lines 36-64, col. 12 line 55 to col. 14 line 25, and col. 14 line 42 to col. 15 line 32); and

(iv) a graphical user interface to present and view patient data and touch screens to the enter patient data at the point of care (col. 5 line 55 to col. 6 line 9, col. 6 lines 36-55, col. 11 lines 30-35, and col. 14 lines 62-65);

(b) capturing patient data electronically at the point of care by health care providers such as physicians or nurse practitioners (col. 2 lines 50-55 and col. 18 line 45);

(c) entering, accessing, processing, analyzing, and annotating data from patient records in real-time at the point of care using an input device such as keyboard, a mouse, or an electronic pen, by a health care provider into the patient data repository (Fig. 1 and 24, col. 5 line 1-28, and col. 7 lines 5-40);

(d) using database software such as Microsoft Access to organize and store data on a server, wherein the data includes appointment data, laboratory test results and x-ray images, prescription information, wherein the data is transferred to medical providers and used by the providers to assist in making diagnosis and administering treatments, and wherein the data is updated using the progress notes (col. 5 line 64 to col. 6 line 55, col. 12 line 55 to col. 14 line 25 and col. 16 lines 35-44); and

(e) communicating with the patient data capture practice guidelines regarding courses of action to obtain a diagnosis and alternative treatments for various conditions to the health care provider (col. 5 lines 1-28, col. 7 lines 40-64).

Evans fails to expressly disclose using software downloaded to a server.

Detjen discloses downloading programs over the Internet to a computer (col. 3 lines 25-65).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to include the features of Detjen within the system of Evans with the motivation of easily and efficiently installing software programs on computers of a network, thus increasing the ease of use for users of the software.

As per the newly added recitations of "creating a plan of care, said plan of care comprising information specifying at least one diagnostic test selected to identify said selected medical condition and scheduling information relating to the diagnostic tests," "communicating the plan of care to the requesting party," "receiving the results of said diagnostic tests in accordance with said plan of care, and storing said results in said database," and "creating a summary of said results for use by a health care provider in selecting a treatment track for treatment of said medical condition based on said test results, and storing said summary in said database," Evans does not expressly disclose these steps. Although as noted above in sections (a)-(e), Evans suggests storing data related to laboratory tests used to make diagnoses and administer treatments.

Joao discloses a processor for processing symptom information and condition information corresponding to a patient, in conjunction with healthcare information,

including data from pulse rate monitors, blood pressure monitors, electrocardiograms, blood-sugar monitors, and scheduled appointments, to generate a diagnostic report and a treatment report, wherein the diagnostic report contains information regarding at least one of symptom information and condition information, and wherein said treatment report contains information regarding a treatment for the diagnosis (col. 16 lines 38-65, col. 17 lines 1-12, col. 18 line 66 to col. 19 line 53, col. 20 lines 51-67, col. 24 lines 21-32, col. 26 lines 7-19, col. 32 lines 11-52, col. 43 line 30 to col. 46 line 36). Further, Joao discloses the diagnostic report containing the healthcare and medical information including data from pulse rate monitors, blood pressure monitors, electrocardiograms, blood-sugar monitors, and scheduled appointments (col. 16 lines 38-65, col. 17 lines 1-12, col. 18 line 66 to col. 19 line 53, col. 20 lines 51-67, col. 24 lines 21-32, col. 26 lines 7-19, col. 32 lines 11-52, col. 43 line 30 to col. 46 line 36). In addition, Joao discloses communicating the diagnostic report and treatment report to a computer or communication device by a requesting party (col. 16 lines 38-65, col. 17 lines 1-12, col. 18 line 66 to col. 19 line 53, col. 20 lines 51-67, col. 24 lines 21-32, col. 26 lines 7-19, col. 32 lines 11-52, col. 43 line 30 to col. 46 line 36). Joao discloses entering the healthcare data obtained from the pulse rate monitors, blood pressure monitors, electrocardiograms, blood-sugar monitors in accordance with the diagnostic report and storing the results in the database (col. 20 line 51 to col. 24 line 32, col. 43 line 30 to col. 46 line 36). Joao discloses after receiving diagnostic report, verifying the diagnostic report and treatment report, and then creating a final diagnostic and treatment report and storing the report in the database, wherein the verification includes generating a

treatment response message comprising information that the treatment is correct (col. 20 line 51 to col. 24 line 32, col. 25 line 1 to col. 26 line 43, col. 43 line 30 to col. 46 line 36).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the teachings of Joao within the method of Evans and Detjen with the motivation of ensuring healthcare providers have the most recent patient information in order to make a proper diagnosis and administer the proper treatments (Joao; col. 1 lines 62-67) and increasing the effectiveness of treatments for patient's by allowing healthcare providers to quickly access and analyze data from remote locations (Evans; col. 2 lines 5-20).

Evans discloses providing instructions for directions for additional tests and procedures by annotating the patients chart (col. 7 lines 5-40). In the discussion above, note the disclosure of Joao related to a diagnosis report and treatment report which is considered by the Examiner to be a form of "plan of care".

Evans, Joao, and Detjen fail to expressly disclose "information specifying a plurality of diagnostic tests to be conducted by a plurality of medical providers, said tests selected to collectively identify said medical condition."

Coli discloses a system for automated ordering access to multiple labs by a physician, wherein the physician determines a diagnosis for a patient, such as "Gastroenteritis", and then selects different profiles for the diagnosis, such as "CPK-BL" and "CHEM WHOLE BLOOD PANEL-BL" tests profiles, wherein the tests are performed by multiple labs depending on the labs capabilities, wherein upon performing the tests,

the test records are received from the lab as well as any other tests performed, and are assembled into a laboratory report in order to make or confirm a diagnosis (Fig. 20, col. 3 lines 1-53, col. 5 lines 57-65, col. 11 lines 26-55, col. 12 lines 11-45, col. 13 lines 13-28, col. 17 line 63 to col. 19 line 53, col. 20 lines 13-45).

At the time the invention was made, it would have been obvious to combine the features of Coli within the method taught collectively Evans, Joao, and Detjen with the motivation of selecting labs for the performance of tests that are capable of performing the requested test, are in a convenient location for the patient, and are participants in the patient's insurance plan (Coli; col. 12 lines 18-45) and to provide an effective means of communication of test results between a physician's office and a remote laboratory (Coli; col. 2 lines 52-63).

(B) As per claim 16, Evans discloses tracking patient data stored in an electronic medical record in the patient data repository including an appointment with a physician, procedures performed within a health care center, such as a hospital (see Scripps Health San Diego in Figure 24), results of x-rays, and prescribed medications (Figure 24, col. 5 line 1 to col. 6 line 55, col. 7 lines 5-40, col. 11 lines 36-64, col. 12 line 55 to col. 13 line 30).

(C) As per claim 17, Evans discloses using point of capture devices, such as desktop computers, laptop computers, or wireless pen computers, over the world wide web for

allowing remote authorized health care providers to access patient records (Figure 24 and col. 12 line 55 to col. 13 line 30).

(D) As per claim 18, Evans discloses allowing health care providers, such as clinics or laboratories, to communicate with the electronic medical records system using modem links and standard v.34 modem devices, such as a US Robotics Sportster 28,800 modem (col. 13 lines 53-56).

(E) As per claim 19, Evans discloses web browsers communicating with remote web servers using a WAN, the world wide web portion of the Internet, and LAN to allow authorized health care providers to access a patient's electronic medical record and to enter and update the patient's electronic medical record from the patient data repository, wherein a system administrator may have a global password access to any patient data for system maintenance and debug purposes (col. 12 line 55 to col. 15 line 32 and col. 16 lines 43).

(F) As per claim 20, Evans discloses physicians having access to only patient records within their specialty, and nurses and staff may have access to only those patient records within their immediate care using a tiered password system (col. 15 lines 20-33).

(G) As per claim 24, Evans and Detjen fail to expressly disclose using an LCD screen. However, Evans includes using touch screens (col. 14 line 63). It is respectfully submitted that LCD screens are a typically used hardware component for viewing data, and the skilled artisan would have found it an obvious modification to include an LCD screen within the system taught collectively by Evans and Detjen with the motivation of allowing health care providers to remotely view patient data (Evans; col. 1 line 53 to col. 2 line 20).

(H) As per claim 25, Detjen includes using an SVGA-compatible color monitor (col. 3 lines 25-38). The motivation for combining Detjen within Evans is as discussed above in claim 1, and incorporated herein.

(I) Claims 29 and 30 repeat the same limitations as claims 14 and 16, and are thus rejected for the same reasons given for those claims.

(J) As per claim 31, Joao discloses the database storing information related to any past diagnosis and using the information stored in the database to treat any diagnosis and symptom (col. 16 lines 37-65, col. 19 lines 13-30). Although Evans and Joao do not expressly disclose the medical condition being gastroesophageal reflux disease, it is respectfully submitted that the system taught collectively by Evans and Joao would include treating any medical conditions. The motivation being to ensure patients are treated for all of their medical conditions.

(K) As per claim 32, Evans discloses annotating patient data in the patient chart by a healthcare provider, wherein the health care provider provides instructions such as directions for additional tests and procedures for the patients (col. 7 lines 5-40).

Declaration under 35 U.S.C. 132

3. At page 11 of the RCE filed 18 May 2004, Applicant argues that secondary consideration of non-obviousness favor patentability of the claims pending within the present application. In particular, Applicant relies on a declaration, namely the Declaration of Chalmers M. Nunn, Jr. MD, filed under 37 C.F.R. 1.132 as evidence of commercial success.

In response, although the Examiner agrees that the courts have made it clear that secondary considerations, such as commercial success, may be relied upon to establish the non-obviousness of an invention, the Examiner respectfully submits that the evidence submitted by Applicant in the form of the declarations filed under 37 C.F.R. 1.132 fail to meet the criteria established under MPEP sections 716.03 through 716.03(b) and 716.02(c-e), for at least the following reasons:

(I) The declarations fail to establish a clear nexus between the alleged commercial success and the invention as claimed. The evidence is not commensurate in scope with the scope of the claims. *In re Tiffin*, 448 F.2d 791, 171 USPQ 294 (1971). In particular, there is nothing that directly ties the statements given in paragraphs 2 and 10

of the declaration of Chalmers M. Nunn, Jr. MD with the language specifically recited in the instant claims.

Applicant's statements at paragraphs 2 and 10 of the declaration of Chalmers M. Nunn, Jr. MD do not appear to correlate to the claimed invention, namely claims 14 and 29, in that the nexus between the elements in the claims and the internet-based integrated healthcare delivery system is not clearly established. For example, Affiant Chalmers M. Nunn, Jr. MD refers to "an internet-based integrated healthcare delivery system" (paragraph 2). However, nowhere in claims 14 and 29 is there a specific recitation of "an internet-based integrated healthcare delivery system". As such, it is noted that the specific features upon which the Affiant (and Applicant) relies as the reasons for commercial success are not recited in the instant claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Further, the courts have held that affidavits or declarations showing commercial success as secondary considerations of non-obviousness to the invention "described and claimed" or other equivalent indefinite language have little or no evidentiary value. *In re Troutman*, 1960 C.D. 308, 126 USPQ 56, 47 CCPA 308. In addition, statements which amount to an affirmation that the claimed subject matter functions as it was intended to function is not relevant to the issue of non-obviousness and provides no objective evidence thereof. See MPEP § 716.

As such, there is no clear and definite nexus between the statements averred by Chalmers M. Nunn, Jr. MD and Applicant's claims.

(II) In order to establish commercial success, the evidence must establish that the alleged commercial success is directly derived from the invention claimed, in a marketplace where the consumer is free to choose on the basis of objective principles, and that such success is not the result of heavy promotion or advertising, shift in advertising, consumption by purchasers normally tied to Applicant or assignee, or other business events extraneous to the merits of the claimed invention. *In re Magneli et al.*, 176 USPQ 305 (CCPA 1973); *In re Noznick et al.*, 178 USPQ 43 (CCPA 1973). Thus, commercial interest can been construed as commercial success only if that interest generated is evidenced to stem from the commercial success directly derived from the invention claimed.

In the present case, the Examiner agrees that based on the declaration of Chalmers M. Nunn, Jr. MD, namely paragraphs 3-10, that there has been an increased number of procedures performed. The declaration states that although Centra Health's financial data is confidential, the gains are obvious given the increase in procedures. However, it is not clear to the Examiner, based on the data in paragraphs 3-10, that the increase in the number of procedures was due to the use of the Internet-based integrated healthcare delivery system. The evidence presented does not rule out the possibility that the marketplace was such that consumption was by purchasers normally tied to Applicant or assignee, and, as such, is insufficient to establish Applicant's allegations that such commercial interest stems from the commercial success directly derived from the invention claimed.

Response to Arguments

4. Applicant's arguments filed 18 May 2004 have been fully considered but they are not persuasive. Applicant's arguments will be addressed below in the order in which they appear in the response filed 18 May 2004.

(A) At pages 9-10, Applicant argues that certain features, namely the newly added features, are not taught by the applied prior art.

In response, In response, all of the limitations which Applicant disputes as missing in the applied references, including the features newly added in the 18 May 2003 amendment, have been fully addressed by the Examiner as either being fully disclosed or obvious in view of the collective teachings of Evans, Joao, Detjen, and/or Coli, based on the logic and sound scientific reasoning of one ordinarily skilled in the art at the time of the invention, as detailed in the remarks and explanations given in the preceding sections of the present Office Action, and incorporated herein. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In addition, it is respectfully submitted that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of

the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., see page 11 of the response filed 18 May 2004, "the present invention provides for the comprehensive and organized treatment of chronic conditions by providing a unified plan of care...The completion status and results of the tests are known by all relevant parties, even if individual tests are performed by different healthcare providers at geographically separate locations...By using this plan of care the present invention integrates the delivery of healthcare services by multiple healthcare providers to a patient so the patient can receive comprehensive treatment for his or her condition without having to resort to self-management of a confusing maze of medical records, appointments, and treatment options) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Conclusion

5. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure. The cited but not applied prior art teaches data processing system which suggests a pattern of medial tests to reduce the number of tests

necessary to confirm or deny a diagnosis (4,731,725) and virtual medical instrument for performing medical diagnostic testing on patients (5,623,925).

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Bleck whose telephone number is (703) 305-3981. The Examiner can normally be reached on Monday-Thursday, 8:00am – 5:30pm, and from 8:30am – 5:00pm on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached at (703) 305-9588.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist whose telephone number is (703) 306-1113.

8. **Any response to this action should be mailed to:**

Commissioner of Patents and Trademarks
Washington, D.C. 20231

Or faxed to:

(703) 872-9306 or (703) 872-9326 [Official communications]

(703) 872-9327 [After Final communications labeled "Box AF"]

(703) 746-8374 [Informal/ Draft communications, labeled "PROPOSED" or "DRAFT"]

Hand-delivered responses should be brought to Crystal Park 5, 2451 Crystal Drive, Arlington, VA, 7th Floor (Receptionist).

CB
September 8, 2004

JOSEPH THOMAS
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TECHNOLOGY CENTER 3600